

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GENENTECH, INC., and CITY OF HOPE

Plaintiffs,

v.

AMGEN INC.

Defendant.

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PUBLIC VERSION FILED: December 13, 2017

C.A. No. 17-1407-GMS

**FIRST AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT
INFRINGEMENT AND DECLARATORY JUDGMENT**

Plaintiffs Genentech, Inc. and City of Hope, by their attorneys, for their

Complaint, allege as follows:

NATURE OF THE CASE

1. Avastin[®] contains a genetically engineered antibody, bevacizumab, that inhibits the proliferation of blood vessels necessary for cancerous tumors to grow. FDA first approved Avastin[®] in 2004. Based on extensive clinical testing by Genentech, Avastin[®] is now approved for use in treating metastatic colon cancer, lung cancer, glioblastoma, ovarian cancer, and cervical cancer. It is one of the top selling medicines in the United States and a critical source of research and development funding for Genentech.

2. Last November, Amgen filed for FDA approval under the Biologics Price Competition and Innovation Act (“BPCIA”), 42 U.S.C. § 262, to commercialize a biosimilar copy of Avastin[®]. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for abbreviated regulatory approval for biosimilars by letting applicants rely on the extensive clinical

testing previously conducted by the innovator company that developed the medicine the applicant wants to copy.

3. Biologic medicines often have extensive patent portfolios associated with them. Avastin[®] is no exception. Genentech's innovative work in developing bevacizumab has been recognized by the Patent Office with dozens of patents covering the antibody itself, methods for its therapeutic use, and processes for the manufacture of therapeutic antibodies.

4. Recognizing the need to protect the patent rights of innovator companies like Genentech, Congress included provisions in the BPCIA to ensure that innovator companies have adequate opportunity to study the proposed biosimilars and the complex manufacturing processes used to make them, and where appropriate, to assert infringement before competing biosimilars come to market. This process, often called the "patent dance," starts when the FDA accepts an application for review, and is supposed to run in parallel with the FDA's review process. The "patent dance" allows parties to narrow or eliminate disputes over infringement prior to approval and ensures the innovator has received enough information about the proposed biosimilar to seek a preliminary injunction should an applicant who receives approval attempt to launch at risk.

5. The statutory protections for Genentech in this case kicked in on January 4, 2017, when the FDA notified Amgen that its Abbreviated Biologic License Application, or "aBLA," had been accepted for review. That gave Amgen twenty days to provide Genentech with "a copy of the application submitted to [FDA] under subsection (k), *and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.*" 42 U.S.C. § 262(l)(2)(A) (emphasis added); *see also id.* § 262(l)(3)(A).

6. Amgen's compliance with this requirement is critical to protecting Genentech's statutory rights. The BPCIA gives Genentech just sixty days after receiving this information to review it before serving Amgen with a list of patents Genentech believes "could reasonably be asserted" against the manufacture, use, sale, offer for sale, or importation of Amgen's proposed biosimilar. 42 U.S.C. § 262(l)(3)(A). An extremely thorough review is critical, because patents not listed generally cannot be asserted in later litigation. 35 U.S.C. § 271(e)(6)(C). The early disclosure requirements also serve to facilitate informed and orderly preliminary injunction proceedings, should that become necessary, after FDA licensure but before the biosimilar product is commercialized.

7. Ignoring the express statutory language, Amgen refused to provide Genentech with anything except its aBLA. Ten days before Amgen's production was due, Genentech provided a list of "other information" that was relevant to its patent assessment, tying each request to the patents implicated. But Amgen ignored this targeted request and took the position that producing the aBLA alone was sufficient under the statute.

8. On February 15, 2017, Genentech sued Amgen for failing to comply with its statutory obligations under the BPCIA, thus hindering Genentech's ability to provide Amgen with a list of patents pursuant to 42 U.S.C. § 262(l)(3)(A). This Court dismissed the action at Amgen's urging for want of subject matter jurisdiction. Genentech proceeded to serve a list of patents pursuant to 42 U.S.C. § 262(l)(3)(A) despite Amgen's non-compliance with 42 U.S.C. § 262(l)(2).

9. On May 23, 2017, Amgen served disclosures purporting to comply with 42 U.S.C. § 262(l)(3)(B). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10. Genentech relied on Amgen's representation, which Amgen made repeatedly. As detailed further below, Amgen violated this binding representation by asserting that the patents [REDACTED] were invalid and by asserting that it could begin marketing six months after October 6, 2017.

11. [REDACTED]

[REDACTED] Genentech inquired repeatedly about the purpose of Amgen's manufacturing activities. Amgen alleged that such activities are protected from infringement because of their relationship to regulatory activities, even though it had completed its clinical testing months earlier. Amgen refused to respond to Genentech's repeated inquiries about the amount of drug substance that Amgen had manufactured. Upon information and belief, and based upon Amgen's repeated refusal to provide information about the purpose and extent of its manufacturing, Genentech alleges that Amgen's activities are not protected from infringement pursuant to 35 U.S.C. § 271(e)(1).

12. On July 22, 2017, Genentech served detailed infringement and validity contentions pursuant to 42 U.S.C. § 262(l)(3)(C) ("Genentech's (l)(3)(C) Contentions"). These contentions span 559 pages and provide particularized detail concerning Amgen's infringement

of numerous patents. The contentions discuss information that Amgen alleges to be confidential. Accordingly, Genentech has not attached the contentions to this pleading but incorporates the contentions by reference.

13. Over the course of the ensuing months, Amgen refused to negotiate concerning the scope of litigation despite the requirements of 42 U.S.C. § 262(l)(4). Amgen purported to require additional time to review Genentech's (l)(3)(C) Contentions, thereby delaying the initiation of negotiations pursuant to 42 U.S.C. § 262(l)(4). Genentech sent multiple letters to Amgen during this period reiterating its willingness to begin the required negotiations. But,

Genentech did not take other steps to accelerate the pace of negotiations, and it refrained from commencing litigation against Amgen.

14. Following the negotiations pursuant to 42 U.S.C. § 262(l)(4), Genentech—and not Amgen—would have had the opportunity to file an action for patent infringement in the appropriate venue of its choosing. Amgen sought to delay the initiation, and, by extension, the termination of those negotiations, in order to prevent Genentech from filing suit. Amgen's purported provision of notice pursuant to 42 U.S.C. § 262(l)(8) and filing of a lawsuit on the same day—before the conclusion of negotiations under 42 U.S.C. § 262(l)(4) that it had stalled unilaterally—constitutes an attempt to deprive Genentech of its statutory right to choose an appropriate venue to remediate Amgen's infringement.

15. Following a lengthy and unexplained delay, Amgen agreed to an in-person meeting to initiate 42 U.S.C. § 262(l)(4) negotiations that was held on September 14, 2017. At that meeting, Genentech proposed to Amgen that the litigation pursuant to 42 U.S.C. § 262(l)(6)

encompass all of the patents asserted in this Complaint. Amgen disagreed, but suggested it would provide a counter-proposal concerning the scope of the litigation.

16. Amgen never sent such a proposal. Instead, on October 2, 2017, Amgen sent Genentech a letter stating that the 15-day window for “good-faith negotiations” had elapsed and that it would “be in touch regarding § 262(l)(5).”

17. On October 6, 2017, Amgen sent Genentech another letter “writing to ask if you are available to conduct § 262(l)(5) negotiations next week,” Amgen offered to “provid[e] the number of patents pursuant to § 262(l)(5)(A) on Monday.” Amgen’s letter did not mention that it had also purported to serve Genentech with a notice pursuant to § 262(l)(8) that it intended to begin commercial marketing. Nor did Amgen’s letter indicate that it had, just hours earlier, filed a lawsuit against Genentech in the Central District of California, seeking a declaratory judgment with respect to all of the patents listed in Genentech’s §262(l)(3)(A) list of patents.

18. The purpose of Amgen’s behavior is manifest. It has deprived Genentech of its plain right under the BPCIA to thoroughly evaluate potential infringement before Amgen’s proposed copy of Avastin[®] comes to market and it seeks to deprive Genentech of its right to select the forum for litigation pursuant to the BPCIA. As a result, Genentech has been forced to evaluate its rights based on an incomplete record and to file this lawsuit to preserve its rights in the face of Amgen’s astonishing conduct.

19. Genentech therefore brings this action for infringement, declaratory judgment, and additional appropriate relief, specifically an order declaring that Amgen’s actions are contrary to the BPCIA and that the manufacture, use, offer for sale, and/or sale of Amgen’s proposed biologic product infringes Genentech’s intellectual property rights.

THE PARTIES

20. Genentech, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases.

21. City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

22. Amgen Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

23. Amgen is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling biologic drug products that are distributed and sold throughout the United States and in the State of Delaware. With respect to biologics, Amgen is both an innovator company with its own drugs and a biosimilar manufacturer hoping to copy drugs invented and developed by others.

JURISDICTION AND VENUE

24. This action for patent infringement arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

25. This Court has personal jurisdiction over Amgen because it is incorporated in the State of Delaware; because Amgen sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 215 in the United States, including in the

State of Delaware; and because Amgen intends to market, distribute, offer for sale, and/or sell ABP 215 in the United States, including in the State of Delaware, deriving substantial revenue therefrom.

26. In addition, Amgen has consented to jurisdiction in the State of Delaware in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Amgen pharmaceutical products in the United States, including in the State of Delaware. This includes cases Amgen has initiated as the plaintiff.

27. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) because Amgen is incorporated in Delaware. In addition, Amgen has consented to venue in this district repeatedly, including in connection with litigation under the BPCIA. In particular, Amgen has consented to venue in this district with respect to an action that, like the instant suit, seeks a declaration that Amgen has violated the BPCIA with respect to its bevacizumab aBLA.

FACTUAL BASIS FOR RELIEF

28. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is “biosimilar” to a previously licensed “reference product” such as Avastin[®]. 42 U.S.C. § 262(k). Biosimilars must be “highly similar to the reference product notwithstanding minor differences in clinically inactive components,” with “no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.” *Id.* § 262(i)(2)(A)-(B). In addition, a biosimilar must use the same mechanism of action as the reference product for the conditions of use prescribed, recommended, or suggested in the reference product’s FDA approved label. *See* 42 U.S.C. § 262(k)(2)(A)(i)(II). The route of administration, dosage form, and strength of a biosimilar must also be the same as those of the reference product. *See id.* § 262(k)(2)(A)(i)(I).

29. The BPCIA reduces the time and expense otherwise required to gain FDA approval by letting an applicant rely on most of the clinical testing used to establish the safety and efficacy of the reference product. The statute also includes extensive provisions to ensure the “reference product sponsor” (*i.e.*, the innovator) has an opportunity to assess the proposed product and the manufacturing processes used to make it, to determine the extent to which there is threatened infringement of the innovator’s patent rights, and if necessary, to vindicate those rights before the biosimilar product comes to market.

30. Genentech, the “reference product sponsor” of Avastin[®], invested many years of effort into the design and development of Avastin[®] and received numerous patents rewarding this research. In addition, as an industry leader with many biologic products besides Avastin[®], Genentech has an extensive patent portfolio covering various innovations generally applicable to the antibody manufacturing process.

THE GENENTECH PATENTS

31. As a result of Amgen’s conduct, Genentech has been forced to assess Amgen’s infringement based on incomplete information. Nevertheless, faced with the risk of being forever barred from asserting patents should a court later find Amgen’s production compliant with the statute, Genentech served on March 24, 2017 a list of 27 patents that Genentech believed could reasonably be asserted against the manufacture, use, sale, offer for sale, or import into the United States of ABP 215. *See* 42 U.S.C. § 262(l)(3)(A). In response to Amgen’s (l)(3)(B) contentions, Genentech declined to serve infringement contentions pursuant to § 262(l)(3)(C) as to two patents.

32. Subsequent to the service of Genentech’s list of patents it believed could reasonably be asserted against ABP 215 pursuant to 42 U.S.C. § 262(l)(3)(A), United States

Patent No. 9,795,672 (“the ’672 patent”) (Exhibit Y hereto), was duly and legally issued on Oct. 24, 2017.

33. Pursuant to 42 U.S.C. § 262(l)(7), on November 2, 2017 Genentech provided to Amgen a supplement to its list of patents pursuant to 42 U.S.C. § 262(l)(3)(A) to include the ’672 patent. Amgen notified Genentech of its contentions pursuant to 42 U.S.C. § 262(l)(3)(B), with respect to this patent by email dated December 1, 2017.

34. Genentech asserted through the patent dance that the following patents have been infringed and will be infringed by the manufacture, use, sale, or offer for sale of ABP 215. The patents-in-suit (“the Asserted Patents”) are:

US Patent No.	Issue Date	First Named Inventor
EX A -- 6,054,297	April 25, 2000	Carter
EX B -- 6,121,428	Sept. 19, 2000	Blank
EX C -- 6,242,177	June 5, 2001	Simmons
EX D -- 6,331,415	Dec. 18, 2001	Cabilly
EX E -- 6,407,213	June 18, 2002	Carter
EX F -- 6,417,335	July 9, 2002	Basey
EX G -- 6,586,206	July 1, 2003	Dixit
EX H -- 6,620,918	Sept. 16, 2003	Ansaldi
EX I -- 6,870,034	March 22, 2005	Breece
EX J -- 6,884,879	April 26, 2005	Baca
EX K -- 7,060,269	June 13, 2006	Baca
EX L -- 7,169,901	Jan. 30, 2007	Baca
EX M -- 7,375,193	May 20, 2008	Baca
EX N -- 7,622,115	Nov. 24, 2009	Fyfe
EX O -- 7,807,799	Oct. 5, 2010	Fahrner
EX P -- 7,923,221	April 12, 2011	Cabilly
EX Q -- 8,044,017	Oct. 25, 2011	Emery

US Patent No.	Issue Date	First Named Inventor
EX R -- 8,460,895	June 11, 2013	Eisenkraetzer
EX S -- 8,512,983	Aug. 20, 2013	Gawlitsek
EX T -- 8,574,869	Nov. 5, 2013	Kao
EX U -- 8,633,302	Jan. 21, 2014	Hepbildikler
EX V -- 8,710,196	April 29, 2014	Emery
EX W -- 9,441,035	Sept. 13, 2016	Carvalhal
EX X -- 9,487,809	Nov. 8, 2016	Zhou
EX Y -- 9,795,672	Oct. 24, 2017	Fyfe

35. Genentech is the owner of all right, title, and interest in the Asserted Patents, with the following exceptions. Genentech and City of Hope are co-owners of U.S. Patent No. 6,331,415 (Exhibit D) and U.S. Patent No. 7,923,221 (Exhibit P). Hoffmann-La Roche, Inc. is the owner of U.S. Patent No. 8,460,895 (Exhibit R) and U.S. Patent No. 8,633,302 (Exhibit U); Genentech is the exclusive licensee of these patents with the sole right to enforce these patents pursuant to a Patent Licensing Agreement between Genentech and Hoffmann-La Roche, Inc. dated January 13, 2017.

Count 1
(Declaratory Judgment that Amgen May Not Market [REDACTED])

36. Genentech incorporates each of the preceding paragraphs as if fully set forth herein.

37. Upon information and belief based upon the allegations contained in the Complaint that it filed in the Central District of California, Amgen contends that it can begin marketing its biosimilar version of Avastin 180 days from October 6, 2017. Amgen's contention contradicts the formal representation it made pursuant to 42 U.S.C. § 262(l)(3)(B), and contained in its letter of May 23, 2017, [REDACTED]

[REDACTED]

38. The representation included in Amgen's disclosure under 42 U.S.C. § 262(l)(3)(B)(ii)(II) that Amgen [REDACTED] enforceable pursuant to the BPCIA, including under 42 U.S.C. § 262(l)(3)(B).

39. The BPCIA prohibits an applicant from commencing commercial marketing of its product prior to the expiration of any patents the applicant has identified pursuant to 42 U.S.C. § 262(l)(3)(B)(ii)(II).

40. There is an actual controversy between the parties concerning whether Amgen may market its biosimilar version of Avastin [REDACTED]

41. Genentech will be irreparably harmed if Amgen is permitted to market its biosimilar version of Avastin [REDACTED]

42. Genentech requests a declaration that Amgen may not market its biosimilar version of Avastin [REDACTED]

Count 2
(Infringement of the '297 Patent)

43. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

44. United States Patent No. 6,054,297 ("the '297 patent") (Exhibit A hereto), was duly and legally issued on April 25, 2000.

45. Amgen has infringed the '297 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States.

46. [REDACTED]
[REDACTED]. Amgen believed, [REDACTED]
[REDACTED] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42

U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]

[REDACTED]

47. Amgen's infringement of the '297 patent was willful.

48. As a result of Amgen's infringement of the '297 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '297 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

49. As a consequence of Amgen's infringement of the '297 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

50. Amgen's willful, wanton, and deliberate infringement of the '297 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 3
(Declaratory Judgment of Infringement of the '297 Patent)

51. Amgen will infringe the '297 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States.

52. Unless Amgen is enjoined from infringing the '297 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 4
(Infringement of the '428 Patent)

53. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

54. United States Patent No. 6,121,428 ("the '428 patent") (Exhibit B hereto), was duly and legally issued on September 19, 2000.

55. Amgen has infringed the '428 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States.

56. [REDACTED]
[REDACTED] Amgen believed, [REDACTED]
[REDACTED], that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]
[REDACTED]

57. Amgen's infringement of the '428 patent was willful.

58. As a result of Amgen's infringement of the '428 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '428 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

59. As a consequence of Amgen's infringement of the '428 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

60. Amgen's willful, wanton, and deliberate infringement of the '428 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 5
(Declaratory Judgment of Infringement of the '428 Patent)

61. Amgen will infringe the '428 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States.

62. Amgen's infringement of the '428 patent will be willful.

63. Unless Amgen is enjoined from infringing the '428 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 6
(Infringement of the '177 Patent)

64. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

65. United States Patent No. 6,242,177 ("the '177 patent") (Exhibit C hereto), was duly and legally issued on June 5, 2001.

66. Amgen has infringed the '177 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States.

67. [REDACTED]
[REDACTED]. Amgen believed, [REDACTED]
[REDACTED] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]
[REDACTED]

68. Amgen's infringement of the '177 patent was willful.

69. As a result of Amgen's infringement of the '177 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '177 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

70. As a consequence of Amgen's infringement of the '177 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

71. Amgen's willful, wanton, and deliberate infringement of the '177 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 7
(Declaratory Judgment of Infringement of the '177 Patent)

72. Amgen will infringe the '177 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States.

73. Amgen's infringement of the '177 patent was willful.

74. Unless Amgen is enjoined from infringing the '177 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 8
(Infringement of the '415 Patent)

75. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

76. United States Patent No. 6,331,415 ("the '415 patent") (Exhibit D hereto), was duly and legally issued on Dec. 18, 2001.

77. Amgen has infringed the '415 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States.

78. [REDACTED]

[REDACTED] Amgen believed, [REDACTED]

[REDACTED], that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]

[REDACTED]

79. Amgen's infringement of the '415 patent was willful.

80. As a result of Amgen's infringement of the '415 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '415 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

81. As a consequence of Amgen's infringement of the '415 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

82. Amgen's willful, wanton, and deliberate infringement of the '415 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 9
(Declaratory Judgment of Infringement of the '415 Patent)

83. Amgen will infringe the '415 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

84. Amgen's infringement of the '415 patent will be willful.

85. Unless Amgen is enjoined from infringing the '415 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 10
(Infringement of the '213 Patent)

86. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

87. United States Patent No. 6,407,213 ("the '213 patent") (Exhibit E hereto), was duly and legally issued on June 18, 2002.

88. Amgen has infringed the '213 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(C) contentions.

89. [REDACTED]

[REDACTED] Amgen believed, [REDACTED]
[REDACTED], that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP215.

90. Amgen's infringement of the '213 patent was willful.

91. As a result of Amgen's infringement of the '213 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '213 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

92. As a consequence of Amgen's infringement of the '213 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

93. Amgen's willful, wanton, and deliberate infringement of the '213 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 11
(Declaratory Judgment of Infringement of the '213 Patent)

94. Amgen will infringe the '213 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

95. Amgen's infringement of the '213 patent will be willful.

96. Unless Amgen is enjoined from infringing the '213 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 12
(Infringement of the '335 Patent)

97. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

98. United States Patent No. 6,417,335 (“the ’335 patent”) (Exhibit F hereto), was duly and legally issued on July 9, 2002.

99. Amgen has infringed the ’335 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

100. [REDACTED]
[REDACTED]. Amgen believed, [REDACTED]
[REDACTED], that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen’s ABP215.

101. Amgen’s infringement of the ’335 patent was willful.

102. As a result of Amgen’s infringement of the ’335 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the ’335 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

103. As a consequence of Amgen’s infringement of the ’335 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

104. Amgen’s willful, wanton, and deliberate infringement of the ’335 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

Count 13
(Declaratory Judgment of Infringement of the '335 Patent)

105. Amgen will infringe the '335 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

106. Amgen's infringement of the '335 patent will be willful.

107. Unless Amgen is enjoined from infringing the '335 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 14
(Infringement of the '206 Patent)

108. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

109. United States Patent No. 6,586,206 ("the '206 patent") (Exhibit G hereto), was duly and legally issued on July 1, 2003.

110. Amgen has infringed the '206 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

111. Amgen's infringement of the '206 patent was willful.

112. As a result of Amgen's infringement of the '206 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '206 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

113. As a consequence of Amgen's infringement of the '206 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

114. Amgen's willful, wanton, and deliberate infringement of the '206 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 15
(Declaratory Judgment of Infringement of the '206 Patent)

115. Amgen will infringe the '206 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

116. Amgen's infringement of the '206 patent will be willful.

117. Unless Amgen is enjoined from infringing the '206 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 16
(Infringement of the '918 Patent)

118. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

119. United States Patent No. 6,620,918 ("the '918 patent") (Exhibit H hereto), was duly and legally issued on Sept. 16, 2003.

120. Amgen has infringed the '918 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

121. Amgen's infringement of the '918 patent was willful.

122. As a result of Amgen's infringement of the '918 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '918 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

123. As a consequence of Amgen's infringement of the '918 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

124. Amgen's willful, wanton, and deliberate infringement of the '918 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 17
(Declaratory Judgment of Infringement of the '918 Patent)

125. Amgen will infringe the '918 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

126. Amgen's infringement of the '918 patent will be willful.

127. Unless Amgen is enjoined from infringing the '918 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 18
(Infringement of the '034 Patent)

128. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

129. United States Patent No. 6,870,034 ("the '034 patent") (Exhibit I hereto), was duly and legally issued on March 22, 2005.

130. Amgen has infringed the '034 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

131. Amgen's infringement of the '034 patent was willful.

132. As a result of Amgen's infringement of the '034 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '034 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

133. As a consequence of Amgen's infringement of the '034 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

134. Amgen's willful, wanton, and deliberate infringement of the '034 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 19
(Declaratory Judgment of Infringement of the '034 Patent)

135. Amgen will infringe the '034 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

136. Amgen's infringement of the '034 patent will be willful.

137. Unless Amgen is enjoined from infringing the '034 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 20
(Infringement of the '879 Patent)

138. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

139. United States Patent No. 6,884,879 ("the '879 patent") (Exhibit J hereto), was duly and legally issued on April 26, 2005.

140. Amgen has infringed the '879 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

141. [REDACTED]

[REDACTED] Amgen believed, [REDACTED]

[REDACTED] hat biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]

[REDACTED]

142. Amgen's infringement of the '879 patent was willful.

143. As a result of Amgen's infringement of the '879 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '879 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

144. As a consequence of Amgen's infringement of the '879 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

145. Amgen's willful, wanton, and deliberate infringement of the '879 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 21
(Declaratory Judgment of Infringement of the '879 Patent)

146. Amgen will infringe the '879 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

147. Amgen's infringement of the '879 patent will be willful.

148. Unless Amgen is enjoined from infringing the '879 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 22
(Declaratory Judgment of Infringement of the '269 Patent)

149. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

150. United States Patent No. 7,060,269 ("the '269 patent") (Exhibit K hereto), was duly and legally issued on June 13, 2006.

151. Amgen knows and intends that its offer for sale and/or sale of ABP 215 in the United States will infringe the '269 patent.

152. ABP 215 is adapted for infringement of the '269 patent and is not a staple article of commerce.

153. Amgen will induce or contribute to infringement of the '269 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling ABP 215 in the United States.

154. [REDACTED]
[REDACTED]. Amgen believed, [REDACTED]
[REDACTED] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP 215.

155. On information and belief, the use of MVASI as described in Amgen's MVASI Label¹ will encourage, suggest, teach, and/or induce the product's use as claimed in the '269 patent.

156. On information and belief, Amgen plans and intends to, and will, actively induce infringement of the '269 patent when it begins commercial marketing of MVASI.

157. On information and belief, Amgen knows that MVASI and its proposed labeling are especially made or adapted for use in infringing the '269 patent, and that MVASI and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Amgen plans and intends to, and will, contribute to infringement of the '269 patent when it begins commercial marketing of MVASI.

158. Unless Amgen is enjoined from infringing the '269 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

¹ Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761028s000lbl.pdf ("MVASI Label").

Count 23
(Infringement of the '901 Patent)

159. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

160. United States Patent No. 7,169,901 ("the '901 patent") (Exhibit L hereto), was duly and legally issued on Jan. 30, 2007.

161. Amgen has infringed the '901 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

162. [REDACTED]

[REDACTED] Amgen believed, [REDACTED]
[REDACTED] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP215.

163. Amgen's infringement of the '901 patent was willful.

164. As a result of Amgen's infringement of the '901 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '901 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

165. As a consequence of Amgen's infringement of the '901 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

166. Amgen's willful, wanton, and deliberate infringement of the '901 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 24
(Declaratory Judgment of Infringement of the '901 Patent)

167. Amgen will infringe the '901 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

168. Amgen's infringement of the '901 patent will be willful.

169. Unless Amgen is enjoined from infringing the '901 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 25
(Infringement of the '193 Patent)

170. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

171. United States Patent No. 7,375,193 ("the '193 patent") (Exhibit M hereto), was duly and legally issued on May 20, 2008.

172. Amgen has infringed the '193 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

173. [REDACTED]

[REDACTED]. Amgen believed, [REDACTED]

[REDACTED] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]

[REDACTED]

174. Amgen's infringement of the '193 patent was willful.

175. As a result of Amgen's infringement of the '193 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '193 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

176. As a consequence of Amgen's infringement of the '193 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

177. Amgen's willful, wanton, and deliberate infringement of the '193 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 26
(Declaratory Judgment of Infringement of the '193 Patent)

178. Amgen will infringe the '193 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

179. Amgen's infringement of the '193 patent will be willful.

180. Unless Amgen is enjoined from infringing the '193 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 27
(Declaratory Judgment of Infringement of the '115 Patent)

181. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

182. United States Patent No. 7,622,115 ("the '115 patent") (Exhibit N hereto), was duly and legally issued on Nov. 24, 2009.

183. Amgen knows and intends that its offer for sale and/or sale of ABP 215 in the United States will infringe the '115 patent.

184. ABP 215 is adapted for infringement of the '115 patent and is not a staple article of commerce.

185. Amgen will induce or contribute to infringement of the '115 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling ABP 215 in the United States.

186. On information and belief, the use of MVASI as described in Amgen's MVASI Label will encourage, suggest, teach, and/or induce the product's use as claimed in the '115 patent.

187. On information and belief, Amgen plans and intends to, and will, actively induce infringement of the '115 patent when it begins commercial marketing of MVASI.

188. On information and belief, Amgen knows that MVASI and its proposed labeling are especially made or adapted for use in infringing the '115 patent, and that MVASI and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Amgen plans and intends to, and will, contribute to infringement of the '115 patent when it begins commercial marketing of MVASI.

189. Unless Amgen is enjoined from infringing the '115 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 28
(Infringement of the '799 Patent)

190. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

191. United States Patent No. 7,807,799 ("the '799 patent") (Exhibit O hereto), was duly and legally issued on Oct. 5, 2010.

192. Amgen has infringed the '799 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

193. [REDACTED]

[REDACTED] Amgen believed, [REDACTED]

[REDACTED], that biosimilar applicants like Amgen must include

all bases for its contentions of non-infringement in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP215.

194. Amgen's infringement of the '799 patent was willful.

195. As a result of Amgen's infringement of the '799 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '799 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

196. As a consequence of Amgen's infringement of the '799 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

197. Amgen's willful, wanton, and deliberate infringement of the '799 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 29
(Declaratory Judgment of Infringement of the '799 Patent)

198. Amgen will infringe the '799 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

199. Amgen's infringement of the '799 patent will be willful.

200. Unless Amgen is enjoined from infringing the '799 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 30
(Infringement of the '221 Patent)

201. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

202. United States Patent No. 7,923,221 ("the '221 patent") (Exhibit P hereto), was duly and legally issued on April 12, 2011.

203. Amgen has infringed the '221 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

204. [REDACTED]

[REDACTED] Amgen believed, [REDACTED]
[REDACTED], that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(l)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP215. [REDACTED]
[REDACTED]

205. Amgen's infringement of the '221 patent was willful.

206. As a result of Amgen's infringement of the '221 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '221 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

207. As a consequence of Amgen's infringement of the '221 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

208. Amgen's willful, wanton, and deliberate infringement of the '221 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 31
(Declaratory Judgment of Infringement of the '221 Patent)

209. Amgen will infringe the '221 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

210. Amgen's infringement of the '221 patent will be willful.

211. Unless Amgen is enjoined from infringing the '221 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 32
(Infringement of the '017 Patent)

212. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

213. United States Patent No. 8,044,017 ("the '017 patent") (Exhibit Q hereto), was duly and legally issued on Oct. 25, 2011.

214. Amgen has infringed the '017 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

215. Amgen's infringement of the '017 patent was willful.

216. As a result of Amgen's infringement of the '017 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '017 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

217. As a consequence of Amgen's infringement of the '017 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

218. Amgen's willful, wanton, and deliberate infringement of the '017 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 33
(Declaratory Judgment of Infringement of the '017 Patent)

219. Amgen will infringe the '017 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

220. Unless Amgen is enjoined from infringing the '017 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 34
(Infringement of the '895 Patent)

221. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

222. United States Patent No. 8,460,895 ("the '895 patent") (Exhibit R hereto), was duly and legally issued on June 11, 2013.

223. Amgen has infringed the '895 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

224. Amgen's infringement of the '895 patent was willful.

225. As a result of Amgen's infringement of the '895 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '895 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

226. As a consequence of Amgen's infringement of the '895 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

227. Amgen's willful, wanton, and deliberate infringement of the '895 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 35
(Declaratory Judgment of Infringement of the '895 Patent)

228. Amgen will infringe the '895 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

229. Unless Amgen is enjoined from infringing the '895 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 36
(Infringement of the '983 Patent)

230. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

231. United States Patent No. 8,512,983 ("the '983 patent") (Exhibit S hereto), was duly and legally issued on Aug. 20, 2013.

232. Amgen has infringed the '983 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

233. Amgen's infringement of the '983 patent was willful.

234. As a result of Amgen's infringement of the '983 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '983 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

235. As a consequence of Amgen's infringement of the '983 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

236. Amgen's willful, wanton, and deliberate infringement of the '983 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 37
(Declaratory Judgment of Infringement of the '983 Patent)

237. Amgen will infringe the '983 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

238. Unless Amgen is enjoined from infringing the '983 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 38
(Infringement of the '869 Patent)

239. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

240. United States Patent No. 8,574,869 ("the '869 patent") (Exhibit T hereto), was duly and legally issued on Nov. 5, 2013.

241. Amgen has infringed the '869 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

242. Amgen's infringement of the '869 patent was willful.

243. As a result of Amgen's infringement of the '869 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '869 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

244. As a consequence of Amgen's infringement of the '869 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

245. Amgen's willful, wanton, and deliberate infringement of the '869 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 39
(Declaratory Judgment of Infringement of the '869 Patent)

246. Amgen will infringe the '869 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

247. Unless Amgen is enjoined from infringing the '869 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 40
(Infringement of the '302 Patent)

248. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

249. United States Patent No. 8,633,302 ("the '302 patent") (Exhibit U hereto), was duly and legally issued on Jan. 21, 2014.

250. Amgen has infringed the '302 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

251. Amgen's infringement of the '302 patent was willful.

252. As a result of Amgen's infringement of the '302 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the '302 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at '302 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

253. Amgen's willful, wanton, and deliberate infringement of the '302 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

Count 41
(Declaratory Judgment of Infringement of the '302 Patent)

254. Amgen will infringe the '302 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

255. Unless Amgen is enjoined from infringing the '302 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 42
(Infringement of the '196 Patent)

256. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

257. United States Patent No. 8,710,196 (“the ’196 patent”) (Exhibit V hereto), was duly and legally issued on April 29, 2014.

258. Amgen has infringed the ’196 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

259. Amgen’s infringement of the ’196 patent was willful.

260. As a result of Amgen’s infringement of the ’196 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the ’196 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

261. As a consequence of Amgen’s infringement of the ’196 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

262. Amgen’s willful, wanton, and deliberate infringement of the ’196 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

Count 43
(Declaratory Judgment of Infringement of the '196 Patent)

263. Amgen will infringe the ’196 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

264. Unless Amgen is enjoined from infringing the ’196 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 44
(Infringement of the '035 Patent)

265. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

266. United States Patent No. 9,441,035 (“the ’035 patent”) (Exhibit W hereto), was duly and legally issued on Sept. 13, 20035 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

267. Amgen’s infringement of the ’035 patent was willful.

268. As a result of Amgen’s infringement of the ’035 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the ’035 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

269. As a consequence of Amgen’s infringement of the ’035 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

270. Amgen’s willful, wanton, and deliberate infringement of the ’035 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

Count 45
(Declaratory Judgment of Infringement of the '035 Patent)

271. Amgen will infringe the ’035 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

272. Unless Amgen is enjoined from infringing the ’035 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 46
(Infringement of the '809 Patent)

273. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

274. United States Patent No. 9,487,809 (“the ’809 patent”) (Exhibit X hereto), was duly and legally issued on Nov. 8, 2016.

275. Amgen has infringed the ’809 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

276. Amgen’s infringement of the ’809 patent was willful.

277. As a result of Amgen’s infringement of the ’809 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from infringing the ’809 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

278. As a consequence of Amgen’s infringement of the ’809 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

279. Amgen’s willful, wanton, and deliberate infringement of the ’809 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

Count 47
(Declaratory Judgment of Infringement of the ’809 Patent)

280. Amgen will infringe the ’809 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech’s (l)(3)(c) contentions.

281. Unless Amgen is enjoined from infringing the ’809 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count 48
(Declaratory Judgment of Infringement of the ’672 Patent)

282. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

283. The ’672 patent was duly and legally issued on Oct. 24, 2017.

284. Genentech is the owner of all right, title, and interest in the ’672 patent.

285. The '672 patent has not yet expired.

286. Pursuant to 42 U.S.C. § 262(l)(7), on November 2, 2017 Genentech provided to Amgen a supplement to its list of patents pursuant to 42 U.S.C. § 262(l)(3)(A) to include the '672 patent. At that time, Genentech provided Amgen with a copy of the '672 patent. Amgen notified Genentech of its contentions pursuant to 42 U.S.C. § 262(l)(3)(B), with respect to this patent by email dated December 1, 2017. Amgen has knowledge of the '672 patent.

287. Amgen has obtained FDA approval under 42 U.S.C. § 262(k) to manufacture, use, offer for sale, and/or sell within the United States, or import into the United States, ABP 215, a biosimilar version of Genentech's Avastin[®] (bevacizumab) product.

288. For example, the sale of MVASI pursuant to its label will contribute to and induce infringement of, *inter alia*, claim 1 of the '672 patent.

289. Claim 1 recites "a method of treating cancer in a patient comprising administering to the patient an effective amount of bevacizumab." For example, Amgen's product is indicated for the treatment of cancer, as set forth in Section 1 of the MVASI Label. For example, Amgen's MVASI Label instructs physicians on the dosage and administration necessary to administer an effective amount, as set forth in Section 2 of the MVASI Label.

290. Claim 1 further recites, "wherein the patient has a grade III hypertensive event resulting from the bevacizumab administration." For example, Amgen's MVASI Label warns physicians in Section 5.7 about the relationship between administration of MVASI and hypertension. Administration of MVASI will result in patients having a grade III hypertensive event resulting from the bevacizumab administration.

291. Claim 1 further recites, "the method further comprising administering to the patient an antihypertensive agent in an amount sufficient to manage the grade III hypertensive

event.” For example, Amgen’s MVASI Label instructs physicians in Section 5.7 in the management of hypertension. Amgen’s MVASI Label instructs and encourages physicians to administer to the patient an antihypertensive agent in an amount sufficient to manage the grade III hypertensive event.

292. Claim 1 further recites, “while continuing to treat the patient with bevacizumab, the treatment being carried out without altering the dosing regimen.” For example, Amgen’s MVASI Label instructs physicians in Sections 2,4 and 5.7 concerning how to administer MVASI while managing hypertension. Amgen’s MVASI Label instructs and encourages physicians to administer to the patient an antihypertensive while continuing to treat the patient with bevacizumab and without altering the dosing regimen.

293. As illustrated above, the use of Amgen’s MVASI as described in the MVASI Label will infringe claim 1 of the ’672 patent.

294. The use of Amgen’s MVASI pursuant to the MVASI Label also will infringe claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, and 18. Amgen’s December 1, 2017 contentions do not contest that administration of ABP 215 pursuant to the MVASI Label would infringe the additional limitations of these dependent claims.

295. On information and belief, the use of MVASI as described in Amgen’s MVASI Label will encourage, suggest, teach, and/or induce the product’s use in connection with antihypertensive therapy as claimed in the ’672 patent.

296. On information and belief, Amgen plans and intends to, and will, actively induce infringement of the ’672 patent when it begins commercial marketing of MVASI.

297. On information and belief, Amgen knows that MVASI and its proposed labeling are especially made or adapted for use in infringing the ’672 patent, and that MVASI and its

proposed labeling are not suitable for substantial noninfringing use. On information and belief, Amgen plans and intends to, and will, contribute to infringement of the '672 patent when it begins commercial marketing of MVASI.

298. ABP 215 is adapted for infringement of the '672 patent and is not a staple article of commerce.

299. Amgen will induce or contribute to infringement of the '672 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling ABP 215 in the United States.

300. Unless Amgen is enjoined from infringing the '672 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Genentech requests the following relief:

(a) A judgment that Amgen's representation under § 262(l)(3)(B)(ii)(II) to refrain from marketing ABP 215 [REDACTED] is binding and that Amgen may begin commercial marketing of ABP 215 [REDACTED]

(b) A judgment that Amgen has infringed the Asserted Patents;

(c) Damages in the form of lost profits but in no event less than a reasonable royalty on past and future infringing sales;

(d) A judgment that the infringement has been willful and an enhancement of damages;

(e) An award for an accounting of damages from Amgen's infringement;

(f) Preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Amgen, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their

successors or assigns from infringing the Asserted Patents, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes the Asserted Patents;

(g) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) An award of Plaintiffs' costs and expenses in this action; and

(i) Such further relief as this court may deem just and proper.

Dated: December 6, 2017

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